IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
MONTGOMERY DIVISION

DEBRA RUBERTI,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 2:20-00874-WKW-JTA**
	)	
ETHICON, INC., et al.,	)	
	)	
Defendants.	)	

PLAINTIFF'S MOTION *IN LIMINE*

COMES NOW Plaintiff, Debra Ruberti, through undersigned counsel, and submits this, her Motion *in Limine*. Plaintiff, before any proceedings before the jury, makes and files this, her Motion *in Limine*, and asks the court, pursuant to the Federal Rules of Evidence ("F.R.E."), not to mention or allow Defendants, Ethicon, Inc. and Johnson & Johnson (collectively "Defendants") to put before the jury, either directly or indirectly, during *voir dire*, opening statement, examination of witnesses, introduction of any evidence, argument, objections before the jury, reading of any portion of the pleadings, or by any other means, or in any other manner inform the jury, or bring to the jury's attention, any of the matters set forth in the numbered paragraphs below, unless or until such matters have been first called to the attention of the court out of the presence and/or hearing of the jury, and a favorable ruling obtained from the Court as to the admissibility of the following:

Motion *in Limine* No. 1: To exclude evidence relating to the United States Food and Drug Administration ("FDA"), including 510(k) clearance of the product in question, or the lack of FDA enforcement action relative to those products.

Plaintiff seeks to preclude Defendants from offering argument, testimony, or evidence of any type relating to the activities of the FDA as it pertains to the product at issue. Such evidence is inadmissible under F.R.E. 401, 402, and 403. The FDA designation of "safe and effective" is a term of art. It is well-established that the FDA's 510(k) "clearance" process is not equivalent to its premarket "approval" process, and only premarket approval results in an FDA finding that a medical device is "safe and effective." Federal courts have repeatedly considered, and subsequently excluded, any and all evidence related to the FDA, because: (1) the FDA's 510(k) process is **not relevant** to tort law; and (2) the prejudicial value of evidence regarding the 510(k) process far outweighs its extremely limited probative value.[1] In fact, the Ethicon MDL Court excluded such evidence every time this issue was raised. The sound reasoning, and previous holdings, should control the present motion and this Court should adopt the prior rulings given that no distinction in the underlying evidence, or changes to the governing law, justifies a different result here.

A. FDA Evidence is Irrelevant and Immaterial under F.R.E. 401 and 402.

The issues in this case involve the defectiveness of design and/or the adequacy of the warnings of Defendants' Tension-free Vaginal Transobturator tape ("TVT-O") device and whether

[1] *Bellew v. Ethicon, Inc*., No. 2:13-cv-22473, 2014 U.S. Dist. LEXIS 165709, at *28 (S.D. W.Va. Nov. 25, 2014) ("In every previous case in these MDLs, this court has excluded evidence regarding the 510(k) clearance process of the product at issue"); *Sutphin v. Ethicon, Inc*., No. 2:14-cv-01379, 2020 U.S. Dist. LEXIS 155868 (S.D. W.Va. Aug. 27, 2020) (exclusion of FDA evidence pertaining to TVT-O); *Huskey v. Ethicon*, 848 F.3d 151, 160-61 (4th Cir. 2017)(holding that information about TVT-O's clearance "***would, at best, have...'tangential[]' relevance to the case***.")(emphasis added); *Hosbrook v. Ethicon, Inc*., No. 3:20-cv-88, 2021 U.S. Dist. LEXIS 186364 (S.D. Ohio Sep. 29, 2021); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D.W. Va. 2014) (holding, "evidence of FDA clearance and enforcement should be excluded under Federal Rules of Evidence 402 and 403").

that product was a cause of Plaintiff's injuries. The FDA's clearance of Defendants' mesh products for sale, and lack of enforcement action relative to those devices, makes no such issue "more or less probable," thereby rendering this evidence inadmissible. *See* F.R.E. 401. Defendants' product at issue in this case was "cleared" through the FDA's 510(k) process, under which products are allowed to be marketed based solely on a finding of "substantial equivalence" to a product on the market prior to 1976, rather than a determination of the product's safety or efficacy. In finding that FDA regulatory evidence would be irrelevant in other cases, courts have observed:

> "Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-79 (1996); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008). There is ample case law discussing *Lohr* and finding that (1) the 510(k) process does not go to whether the product is safe and effective and (2) the 510(k) process does not impose any requirements on its own."

In re C. R. Bard, Inc., No. MDL No. 2187, 2013 U.S. Dist. LEXIS 183718 (S.D. W. Va. July 1, 2013) (collecting cases). The decision to exclude evidence regarding the 510(k) clearance process, or subsequent FDA enforcement actions, was – *and is here* – consistent with prior rulings of other courts, including previous trials related to the same (or similar) products against the same Defendants. *Supra* at Fn 1. Moreover, as several courts have recognized, there is indeed a wealth of authority holding that the FDA's 510(k) process is not related to product safety or efficacy, as well as abundant case law holding that there are no requirements imposed by way of the FDA 510(k) process.

B. FDA Evidence Is Inadmissible Under F.R.E. 403.

In addition to being irrelevant to the issues in this case, any probative value that might be garnered through presenting this evidence would be substantially outweighed by the danger of unfair prejudice and the risk of confusing the jury. For this reason, the circuit courts have upheld similar rulings from district courts who have determined that FDA evidence in pelvic mesh trials

was correctly omitted under Rule 403.

> "Bard's first claim[s]. . . the district court abused its discretion by granting Cisson's motion in limine . . . to exclude all evidence that Bard had complied with the FDA's 510(k) process. Bard sought to admit the evidence to show that its conduct was reasonable. Bard argued that this was relevant to its defense to the design defect . . . as well as to the question of punitive damages. The district court excluded the evidence under Federal Rule of Evidence 402 for lack of relevance, and under Rule 403 for being substantially more prejudicial than probative. ***We affirm the court's ruling based on Rule 403*** . . ."

In re C. R. Bard, Inc., No. MDL No. 2187, 2013 U.S. Dist. LEXIS 183718, 919 (S.D. W. Va. July 1, 2013) (emphasis added). Other courts have also agreed with the sound reasoning, "the prejudicial value of evidence regarding the 510(k) process far outweighs its probative value." *Sanchez v. Boston Scientific Corp.,* No. 2:12-cv-05762, 2015 WL 631289, at *2 (S.D.W. Va. Feb. 12, 2015) (finding 510(k) evidence is inadmissible because of its potential to confuse the issues and mislead the jury); *see also Williams v. Ethicon, Inc*., CIVIL ACTION NO. 2:12-cv-511 (S.D.W. Va. Dec. 22, 2016) ("Even if the 510(k) process were relevant, the court would exclude this evidence under Rule 403. Any kernel of relevance is outweighed by "the very substantial dangers of misleading the jury and confusing the issues.") (citing *In re C. R. Bard*, 810 F.3d 913, 922 (4th Cir. 2016) (affirming the court's exclusion of 510(k) evidence)); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D.W. Va. 2014) (holding "Admission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims. The prejudicial value of evidence regarding the 510(k) process far outweighs its probative value."). Ethicon's arguments for the admissibility of such evidence have been repeatedly rejected, and the exclusion of that evidence has been affirmed under F.R.E. 403. The Fourth Circuit agreed with the District Court's rationale and affirmed under Rule 403, holding the Court did not abuse its discretion on wholesale exclusion of FDA evidence in products cases involving pelvic mesh. *In re C.R. Bard*, 810 F.3d at 919.

Motion *in Limine* No. 2: To bar completely, or limit significantly, the testimony of Ethicon's regulatory expert, Timothy Ulatowski.

Timothy Ulatowski, Ethicon's "regulatory expert," should be barred from testifying or, at a minimum, have his testimony significantly limited. Mr. Ulatowski's opinions are irrelevant to the issues in this trial and are based on speculation and/or evidence and testimony that should be deemed inadmissible pursuant to the F.R.E. and Plaintiff's MIL No. 1 above.

Mr. Ulatowski provides no testimony that makes any issue in this case "more or less probable," thereby rendering this evidence inadmissible. *See* F.R.E. 401. Mr. Ulatowski, a former FDA employee, offers opinions based on hearsay and his speculative beliefs about whether the Defendants' actions complied with FDA regulations. For example, Mr. Ulatowski offers the following paraphrased opinions:

1. FDA recall of predicate device had no regulatory impact on the TVT-O;
2. FDA still believes polypropylene is safe and effective;
3. Changing TVT-O material would likely require a new 510(k) submission;
4. There was no reason for FDA to recommend label changes;
5. FDA supports Defendant's interpretation regarding purpose of patient brochures;
6. FDA does not include regulatory requirements related to patient brochures;
7. TVT-O was adequately manufactured in accordance with FDA requirements;
8. Defendant's complaint department complied with FDA regulations;
9. Defendant's complaint department complied with MDR requirements;
10. Defendant complied with FDA premarket requirements;
11. Product labeling is compliant with FDA requirements;
12. Defendant's risk management protocol complies with regulations;

13. 510(k) clearance incorporates safe and effectiveness evaluation;

14. Increase in TVT-O MDR was due to litigation and media; and

15. Safety of laser cut mesh was properly verified according to FDA regulations.

These opinions do not make any issue in this trial more or less probable and are therefore not relevant. Whether Defendants complied with Mr. Ulatowski's interpretation of the FDA regulations pertaining to labeling, whether the complaint department adequately complied with regulations, whether the device was properly manufactured, and all other opinions discussed above do not make it more or less probable that the device was defective in its design, nor do they bear any connection to whether the device was a cause of Plaintiff's injuries. Additionally, Mr. Ulatowski's opinions are based on hearsay and speculation. Notably, Mr. Ulatowski's 13th opinion is in direct opposition to rulings of several courts.[2] Based on the foregoing, Mr. Ulatowski should be precluded from testifying.

[2] "Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-79 (1996); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008). There is ample case law discussing *Lohr* and finding that (1) the 510(k) process does not go to whether the product is safe and effective and (2) the 510(k) process does not impose any requirements on its own." *In re C. R. Bard, Inc.,* No. MDL No. 2187, 2013 U.S. Dist. LEXIS 183718 (S.D. W. Va. July 1, 2013) (collecting cases).

Motion *in Limine* No. 3: To exclude evidence related to the history of polypropylene use in the human body.

Plaintiff anticipates that Defendants will argue to the jury that the TVT-O is not defective, in part, based on the position that the base material, polypropylene, has been "safely" used in the human body in sutures and in hernia mesh for many years. Permitting the defense to open this door with a broad, generalized reference to a "long history" of safe use of polypropylene (lumping together all formulations and uses throughout the body) would implicate massive, imprecise hearsay, which would require extensive cross-examination and rebuttal evidence in order to properly explain the irrelevance and misleading nature of that vague but powerful assertion to the jury. This will divert the jury's attention from the relevant issues, confuse and mislead the jury, and create a "mini trial" or "sideshow" on this issue. F.R.E. 403.

Whether, or to what extent, polypropylene may have been used in the human body as sutures, or for hernia mesh in the abdomen, in general, does not disprove any of the claims in this case. The liability issues in this case center on whether the TVT-O system itself is defective - as used to support pelvic organs - and whether Ethicon failed to warn of the risks related to that device.

Generalized statements about the safety of other products are irrelevant, prejudicial, and inherently confusing. They would preclude the making of precise objections as well as hinder focused cross-examination. For example, if the testimony concerned the use of polypropylene mesh to treat hernias, it would be met by countering testimony, such as the deposition testimony of Jim Hart, Chief Medical Officer of the Johnson & Johnson Global Surgery Group, who clearly testified that the use of hernia mesh is not "completely predictive because they are two different anatomic areas." (Exhibit 1 – Deposition Transcript - Jim Hart 12/20/13 at 732:24-733:17).

Without specific frames of reference, plaintiff could not efficiently rebut Defendants' assertions, and this would lead to a significant waste of the Court's, and jurors' time, and will divert the focus to irrelevant, ancillary matters.

But even fairly specific arguments about other products should be precluded, as they will only waste time, and potentially confuse the jury. *See* F.R.E. 403. Should the Court be inclined to consider allowing Defendants to defend the product at issue based on the unrelated use of polypropylene in other unrelated products, such as sutures or hernia mesh, it should significantly limit that defense, provide clear instructions to the jury regarding the limited purpose of the evidence, and require that a proffer be made before trial so that additional objections specific to the evidence can be addressed in advance, rather than when the jury is hearing the case.

Motion *in Limine* No. 4: To exclude testimony that alleges that TVT-O, or other TVT devices, are the "gold standard" for treatment of stress urinary incontinence ("SUI").

Many defense witnesses have offered testimony at deposition asserting their belief that the TVT-line of products represent the "gold standard" for the treatment of SUI. (*See e.g.,* Exhibit 2 – Depo Transcript - Jim Hart 12/20/13 at 904:6-10; Exhibit 3 – Depo Transcript - Joerg Holste 12/20/13 at 175:20-25; Exhibit 4 – Deposition Transcript – David Robinson 9/11/13 at 1152:6-12; Exhibit 5 – Deposition Transcript – Dan Smith 8/21/13 at 575:22-576:2)

This term of art and vague assertion of superiority cannot be definitively quantified or proven to be true based on the evidence and therefore constitutes pure speculation which should be excluded. F.R.E. 602. Furthermore, the prejudicial effect of such testimony would far outweigh any probative value. F.R.E. 403. For these reasons, any testimony or evidence that alleges that the TVT line of products, or the TVT-O in particular, is the "gold standard" for treating SUI, should be excluded.

Motion *in Limine* No. 5: To exclude testimony that alleges that complications related to the TVT-O device are "rare."

Many defense witnesses, including corporate designee, Piet Hinoul, routinely acknowledge the severe complications that occur related to the TVT-O, however, in doing so, these witnesses often add a caveat that the complications only occur "rarely" or "very rarely." (Exhibit 6 – Deposition Transcript - Piet Hinoul 4/6/12 at 512:12-21). However, Ethicon has no evidence to support such an assertion, since Ethicon admits that it does not actually know how frequently such complications occur. Axel Arnaud of Medical Affairs could not point to any effort by Ethicon to quantify the number of women who would suffer serious complications. (Exhibit 7 – Deposition Transcript - Axel Arnaud 11/15/12 at 222:6-13), and Piet Hinoul confessed that Ethicon had no data as to the number of women who have suffered serious complications. (Exhibit 8 – Deposition Transcript - Piet Hinoul 4/5/12 at 190:11-18). These admissions further confirm that any assertions from Defendants as to the supposed "rarity" of the complications are purely speculative and wholly improper. F.R.E. 602 and 701. No defense witness or attorney should make any such assertions – rather, they should be limited to discussing specific rates or frequencies of complications to the extent those facts and figures are documented in specific studies, subject to cross-examination.

Motion *in Limine* No. 6: To exclude evidence and testimony comparing the TVT-O device to other mesh devices that are designed for other purposes.

To the extent that Defendants intend to submit evidence regarding the safety and efficacy of, medical literature regarding, and anecdotal evidence related to, other devices (e.g., Prolift, Prolift +M, etc.) such evidence should be precluded under F.R.E. 401 and 403. These other devices are significantly and materially different from the TVT-O, which is the device at issue, and Defendants should not be permitted to defend on this basis. If permitted, this will necessitate a wasteful "mini-trial" regarding the various differences between these devices. It would also result in the need for the plaintiffs to submit substantial evidence as to any defects, risks, or dangers related to the other devices as well. This additional evidence would add unnecessary confusion and waste precious time and should therefore be excluded under F.R.E. 403.

Aside from the practical issues, the Court should preclude this tactic based on Ethicon's affirmative representation to the FDA that the Prolift should not be compared in any way to the TVT devices:

> TVT (Tension-free Vaginal Tape) mesh is a suburethral sling indicated for stress urinary incontinence (SUI) and is not a claimed predicate of the proposed PROLIFT or PROLIFT +M systems. TVT is not used for the same indication, and it is not used in the same anatomical location. In addition, TVT mesh is not the same mesh as either GYNECARE PROLIFT or GYNECARE PROLIFT +M mesh. **Therefore, the company does not believe that comparisons of meshes used for incontinence versus pelvic organ prolapse surgeries are appropriate.**

(Exhibit 9 - September 20, 2007, Memorandum letter from Ethicon regulatory affairs project manager Bryan Lisa to Jiyoung Dang, Ph.D. of the FDA) (emphasis added).

In addition, Axel Arnaud, an Ethicon medical director, and one of the inventors of the Prolift device, testified that the TVT is **not** a suitable point of comparison:

> Q. There's a discussion there of suburethral sling procedures, procedures for urinary incontinence?
>
> A. Yes. Okay.
>
> Q. And Dr. Altman says, "It is, however, important to consider the different anatomical conditions associated with pelvic organ prolapse...**compared with suburethral tapes, biomaterials used at pelvic organ prolapse repair increase the biomaterial load considerably because of the increased size of the mesh." And you agree with that. Correct?**
>
> A. I do.
>
> Q. They say, "This may increase the risk for adverse tissue reactions and biomaterial-associated complications." You agree with that. Correct?
>
> A. Yes. This is obvious.
>
> Q. **"Although the polypropylene compound used for TVT® and transvaginal mesh is identical, other characteristics, such as elasticity and pore size, differ."** You agree with that statement. Correct?
>
> A. Yes.
>
> Q. And then they say, **"One should, therefore, not assume that the biomaterial properties are the same for the two procedures** and results from incontinence surgery may not be directly applicable to pelvic organ prolapse surgery." You agree with that statement. Correct?
>
> A. Yes.

(Ex. 10 – Deposition Transcript - Axel Arnaud 11/16/12 at 357:4-358:12) (emphasis added).

Therefore, defendants should not be permitted to rely at all on these other devices, or their clinical data, literature, or other such evidence in defense of this case.

Motion *in Limine* No. 7: To exclude evidence and testimony related to what was taught to physicians in "professional education."

Plaintiff anticipates that when deficiencies in the IFU, and other labels and related documents, are pointed out to Ethicon's fact and expert witnesses, they will vaguely respond that additional information was provided to physicians through "professional education." This testimony and argument should be precluded since it would be irrelevant and blatant hearsay, without any specificity or reliability. F.R.E. 401 and 802. In the absence of proof that a document was actually used in professional education (and when, how, and by whom it was used), such blanket hearsay references should be completely precluded. Ethicon cannot prove these foundational facts since Ethicon has been unable to provide information to prove what time period the professional education documents were used or who used them; thus, this type of testimony would be improper and should be excluded.

Motion *in Limine* No. 8: **To exclude evidence and testimony related to what "pelvic surgeons know" regarding risks or benefits of procedures or devices.**

Any reference to what pelvic surgeon may or may not generally know, with regard to the risks and benefits of the device at issue, is based entirely on inadmissible hearsay and blatant speculation. F.R.E. 602 and 802. In addition to the hearsay and speculation issues, any probative value that might possibly be attached to this evidence would by substantially outweighed by its unfairly prejudicial effect and the risk that this evidence would cause confusion among the jury. F.R.E. 403. This speculative and unsubstantiated evidence should therefore be excluded in accordance with FRE 403, 602, and 802.

Motion *in Limine* No. 9: To exclude evidence of Defendants' prior or unrelated "Good Acts" or "Good Reputation."

Defendants may attempt to offer evidence or testimony regarding prior acts of public benefit (e.g., community employment, charitable donations of money, and medical contributions, such as the development of new products) that are wholly unrelated to the TVT-O, or this case, and are offered in an effort to convey a general "good company" reputation. Pursuant to F.R.E. 402 and 403, this type of evidence is not relevant to Plaintiff's claims and is unduly prejudicial. Additionally, because Defendants could only be attempting to show that they were acting in accordance with their "good" character, this evidence is inadmissible under F.R.E. 402, 403, and 404.

I. "Good Acts" and "Good Reputation" testimony or evidence is irrelevant – F.R.E. 401.

To be admissible, evidence must first be relevant. Relevant evidence means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more or less probable than it would be without evidence. F.R.E. 401. Evidence of "good acts," "good reputation," or contributions to society, is completely irrelevant to any of Plaintiff's claims in this case. Even if such "good company" arguments were accepted as true, they would have no effect on the ultimate issue in this case — whether Defendants' TVT-O device injured Plaintiff, Debra Ruberti. This evidence does no more than provide unrelated events in the company's history with the intent of capitalizing on the favorable nature of the prior, unrelated good acts. Without a showing of any relevance to Defendants' liability for Plaintiff's injuries, this evidence should be excluded.

II. "Good acts" and "Good reputation" testimony or evidence is overly prejudicial

Evidence of "good acts" or "good reputation" should also be excluded under F.R.E. 403. The potential evidence has nominal probative value, if any; it is also unduly prejudicial, confuses the issues, and is likely to mislead the jury. Evidence of Defendants' unrelated "good acts" likely would mislead the jury into believing that Defendants do not have the propensity to do wrong. As the commentary to Rule 403 states, "unfair prejudice is an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." These "good acts" have no bearing on Defendants' liability, and therefore, can only be used to evoke admiration for the company's history and past good deeds in the hope of improperly influencing the jury's decision as to liability.

Admission poses a risk that the "emotions of the jury will be excited to irrational behavior, and that this risk is disproportionate to the probative value of the offered evidence." Because the risk of unfair prejudice outweighs the legitimate uses of the evidence, such evidence should be excluded under F.R.E. 403.

III. "Good Acts" and "Good Reputation" testimony is improper propensity evidence

Under F.R.E. 404(a), evidence of a party's character is not admissible to prove that on a particular occasion the party acted in accordance with that character or trait. Moreover, proof of other specific acts is inadmissible. F.R.E. 404(b). Defendants "cannot prove [a] pertinent character trait (of being 'good') by offering evidence of specific instances of good conduct." *United States v. Crockett*, 586 F. Supp. 2d 877, 884 (E.D. Mich. 2008).

This Court should exclude evidence of Defendants' prior good acts or business conduct when it is used to show conformity with such behavior on this occasion. The fact that Defendants purportedly employed individuals in the community, made charitable contributions, or distributed some medical benefit to society, does not bear on Defendants' liability with respect to injuries suffered by Plaintiff. These specific acts of good character are inadmissible under Rule 404(b) to prove Defendant's action in conformity therewith. The natural inclination of pharmaceutical manufacturing defendants is to shift the focus of trial from the Plaintiff, their injuries, and the products causing those injuries to the companies, their beneficial products, their good work for society at large, and the negative implications on individual jury members that a verdict for Plaintiff might cause. Such an approach would ensure that this trial devolves from a genuine effort to determine whether the medical device is unreasonably dangerous or defective into "mini-trials" on whether Defendants' other products and conduct make the company a good social actor.

In a similar product liability case against the same Defendants and based in part on Defendants' stipulation that its "good acts" evidence would relate solely to development of relevant products (whatever that means), the Court granted this motion in part but denied it with respect to evidence related to product development, finding the Court could not evaluate the relevance of such evidence *until its admission were sought*. *Bellew v. Ethicon, Inc.*, Civ. Act. No. 2:13-cv-22473, 2014 WL 6680356, at *7 (S.D.W. Va. Nov. 25, 2014) (emphasis added). But that is precisely why an order *in limine* is appropriate here. Such an order does not forever exclude Defendants from introducing evidence but is merely "an order to approach the bench and seek leave from the Court prior to presenting the evidence covered by the order to the jury." *Corelogic Info. Soluts., Inc. v. Fiserv, Inc.*, No. 2:10-CV-132-RSP, 2012 WL 4761739, at *1 (E.D. Tex. Sept. 20, 2012). If the Court waits until after Defendants begin explicating their "good product

development" story before ruling, the prejudice may have already occurred, and Plaintiff would be put in the unenviable position of appearing to conceal the end of the story Defendants have already begun by interspersing an objection, thereby drawing attention to the very evidence Plaintiff seeks to exclude. *See, e.g., Wilson v. Williams*, 182 F.3d 562, 566 (7th Cir. 1999) ("Motions *in limine* are designed to avoid the delay and occasional prejudice caused by objections and offers of proof at trial."). Therefore, Plaintiff respectfully requests that this Court rule in favor of this motion and preclude Defendants' from presenting any such reputation evidence unless and until the Defendants' first seek a positive ruling and permission to illicit such evidence from this Court.

Motion *in Limine* No. 10: To exclude testimony regarding the number of randomized controlled trials that allegedly support the safety of TVT-O products.

Defendants may attempt to make claims regarding the number of randomized controlled trials that purportedly support the safety and efficacy of TVT-O for the treatment of SUI. Plaintiff respectfully requests that the Court prohibit evidence or argument advancing such claims under F.R.E. 801 and 403, as it would be inadmissible hearsay, confusing to the jury, a waste of time, and unfairly prejudicial.

Hearsay is an out-of-court statement offered to prove the truth of the matter asserted. F.R.E. 801(c). Any statement by a witness regarding the subject and/or conclusions of a randomized control trial - such as a statement that a certain number of randomized controlled trials supported the safety and/or efficacy of TVT-O - would constitute hearsay. The defense may argue that such a statement would fall under the learned treatise exception to the hearsay rule, which provides that the following evidence is not excluded:

> **(18) Statements in Learned Treatises, Periodicals, or Pamphlets.** A statement contained in a treatise, periodical, or pamphlet if:
>
> (A) the statement is called to the attention of an expert witness on cross-examination or relied on by the expert on direct examination; and
>
> (B) the publication is established as a reliable authority by the expert's admission or testimony, by another expert's testimony, or by judicial notice.
>
> If admitted, the statement may be read into evidence but not received as an exhibit.
>
> F.R.E. 803(18).

Testimony regarding the number of randomized controlled trials that purportedly support the safety and efficacy of TVT-O devices would not fall within the learned treatise exception. Such testimony would not be a statement from a particular publication that is read

into evidence. Rather, such testimony would be the witness's opinion and summary of numerous randomized controlled trials, globally, which would be improper.

Plus, even if the learned treatise exception did apply, each such trial – and certain statements contained therein - would have to be addressed individually. Not only does F.R.E. 803(18) require it, testimony that a certain number of randomized controlled trials support the safety and efficacy of TVT-O would also be misleading and unreliable. Randomized controlled trials differ widely with respect to a variety of factors, such as the number of study subjects, the length of the study, and the definition of "cure rate."

Because randomized controlled trials vary and have limitations, even if statements within a randomized control trial were admissible, they would only be admissible individually. They should not be lumped together in the form of a statement that a certain number of trials are supportive of the safety and/or efficacy of the TVT-O product on the whole. Moreover, none of Defendants' experts have testified that he/she has reviewed and analyzed each and every randomized control trial involving TVT-O products. For this additional reason, none of Defendants' witnesses should be permitted to testify as to the total number of randomized control trials that support the safety and efficacy of TVT-O.

Finally, testimony as to the number of trials supporting TVT-O's alleged safety or efficacy has little, if any, probative value; yet the danger of unfair prejudice from Ethicon telling the jury that a large number of trials show that the TVT-O is safe and effective is exceedingly high. Thus, in addition to being inadmissible hearsay; statements and testimony about the number of clinical trials that allegedly support TVT-O's alleged safety and efficacy should be excluded under several aspects of the Rule 403 balancing test.

Motion *in Limine* No. 11: To preclude Defendants or defense counsel from offering testimony or evidence related to the number of women allegedly treated with pelvic mesh and/or the number of women allegedly treated with mesh for stress urinary incontinence.

To the extent that Defendants intend to offer evidence or testimony related to the number of TVT devices (or TVT-O specifically) that have been sold to healthcare providers and facilities in an effort to signal to the jury that a vast quantity of these devices have been used to treat women, is misleading and inappropriate. The number of units of the medical device at issue (TVT-O) sold does not reliably indicate the number of women actually receiving said medical device for treatment of the condition or conditions at issue. Furthermore, the evidence would be entirely misleading given that just because a unit or device is sold, does not necessarily mean that the device was used. Thus, any such reference would be purely speculative and thus, unfairly prejudicial. F.R.E. 403. Lastly, the number of units/devices sold is not relevant to the particular issues raised in the present case. F.R.E. 402.

Motion *in Limine* No. 12: To preclude Defendants or defense counsel from offering testimony or evidence that the TVT-O at issue has been "implanted in millions of women around the world."

To the extent that Defendants intend to offer evidence or testimony related to the number of TVT devices (or TVT-O specifically) that have been implanted in other women to support their belief that the device is safe, would be misleading and prejudicial. F.R.E. 403. The experience of other unnamed women who allegedly have been implanted with the medical devices at issue (regardless of the device name referred to and/or regardless of whether the name referred to is used as a generic description, with different polypropylene products) is not relevant to Plaintiff's specific injuries. Without evidence of how many women suffered injury as a result of the device, any testimony or evidence offered to claim that the device has been "implanted in millions of women around the world" would be wholly irrelevant and the prejudicial effect of such testimony would substantially outweigh any probative value, of which there is none. F.R.E. 401 and 403.

Furthermore, as Plaintiff cannot possibly evaluate the effect of the device on those women, nor explore how many of those women have also suffered injuries, including those that would be similar to those of Plaintiff, any reference or inference that could be derived from such evidence would be skewed by this hinderance and thus would be unfairly prejudicial and would invariably mislead and confuse the jury. F.R.E. 402 and 403.

Motion *in Limine* No. 13: To preclude Defendants and their counsel from offering argument, evidence, or testimony regarding whether the TVT-O is still on the market.

Just as Courts have excluded evidence that products like the Prolift have been removed from the market, it should exclude evidence that products like the TVT remain on the market. *See Bellew v. Ethicon, Inc.*, Civ. Act. No. 2:13-cv-22473, 2014 WL 6680356, at *1 (S.D.W. Va. Nov. 25, 2014). Defendants in *Bellew* acknowledged they removed the Prolift, in part, to avoid conducting the clinical study required by the FDA's 522 order and thus the adverse publicity that could occur with continued sales. (Ex. 11 - *Bellew v. Ethicon, Inc.*, Case No. 2:13-cv-22473, Document No. 207 (Oct. 24, 2014) at 26).[3] In granting Defendants' motion to exclude evidence of product removal, the Court reasoned that allowing such evidence could result in a discussion of FDA actions and their adequacy, a result that had previously led to a mistrial in the *Cisson* case. *Bellew*, 2014 WL 6680356 at *5.

Precisely the same concern dictates exclusion of any suggestion that the TVT-O is still on the market. The introduction of such evidence would suggest that the FDA approves of the product and its safety and efficacy. Even if that were not the reason for which defendants will claim the evidence is relevant, we all know the jury would associate any statement that the product remains on the market with FDA endorsement. Courts have recognized, both in denying Defendants' motions for summary judgment on preemption and in excluding Defendants from discussing their products' approval, that the 510(k) approval involves only "cursory" review of a product and not the "rigorous investigation" required to secure premarket approval. *Bellew*, 2014 WL 6674424 at

[3]Defendants contend that multiple business reasons also militated toward Prolift removal. However, defendant's regulatory affairs executive admitted that removal of the Prolift was part of a *quid pro quo* that prevented Ethicon from being forced to conduct a clinical trial pursuant to the FDA's 522 Order. Ethicon initially responded to this order by attempting to justify the Prolift using two studies that had been thoroughly debunked and were ultimately rejected by the FDA. Ethicon agreed to discontinue Prolift sales when it realized it would have to conduct a study establishing efficacy and safety to satisfy the FDA's mandate. (*Bellew*, *supra*, Document No. 199 (Oct. 24, 2014) at 1-3).

*2. Consequently, the Court precluded evidence regarding 510(k) clearance in every previous trial case, recognizing that such evidence would mislead the jury into believing the FDA had found defendants' products to be safe and effective. *Id.* at *10 & n. 5.[4] And the Court has recognized that introduction of FDA issues could result in the mistrial, as was granted in *Cisson*. *Id.* at *5.

Statements that the product remains on the market are a backdoor way of telling the jury through insinuation and inference that the FDA has approved, and continues to approve, the product. The only way Plaintiff could combat this would be to indict the 510(k) process and point out that FDA clearance under this section says nothing about the product's safety and efficacy, and to further explain the marked difference between FDA approval under the PMA process and "clearance" under the 510(k) review process. The Court must already determine whether discussion of the 510(k) process would serve to mislead and confuse the jury. MIL 1 *supra*. But even more prejudice would occur if Defendants were permitted to imply that the product still has FDA "approval" and Plaintiffs were not permitted to point out the limitations to the FDA clearance process under 510(k).

If statements that the product is still on the market were allowed, Plaintiff would also be entitled to counter those statements by showing that the warnings that now accompany the TVT products are far stronger than they were when the product was originally cleared, thus supporting their position that even the FDA now has its reservations about the device. Not permitting such evidence would severely prejudice Plaintiff by allowing Defendants to erroneously suggest that the FDA's perceptions of the TVT have remained unaltered. In the Prempro MDL proceedings,

[4]Any claim that continuation of the product somehow supports Defendants' "gold standard" claim, which Plaintiff has also requested be excluded, would be without merit. One can argue that a certain device was the gold standard without suggesting the product is still sold today. And even if continued sale is somehow tangentially relevant to defendants' claim, the probative value of the evidence is outweighed by Plaintiffs' need to combat the evidence with a discussion of the inadequacy of the FDA's 510(k) approval process, a result the Court has repeatedly eschewed. (*See* text, *infra*.)

the MDL court held that any discussion by Defendants regarding Prempro's continued sale would open the door to Plaintiffs showing that current warnings are substantially different than the warnings that accompanied the product when it was sold to Plaintiffs, so the jury is not left with the mistaken impression that the FDA's perceptions of the product have not changed.[5]

Statements about the continuation of the product on the market could only serve to suggest FDA endorsement of the product, which is far from the truth. Plaintiff would have to be permitted to counter such an inference with proof that the FDA's clearance process was lax, and the FDA failed to require the kinds of efficacy and safety testing it has required for other devices. The jury cannot be left to conclude that because the FDA "approves" of this device, the device cannot be defective, particularly when that is not factual at all. Given the, at best, tangentially relevant nature of statements about the product remaining on the market, the prejudice inherent in such statements outweighs their probative value. F.R.E. 403.

[5] Transcript, *In re Prempro Prods. Liab. Litig.*, Case No. 03-1507 (E.D. Ark. Sept. 24, 2010)("I realize that labels don't usually come in, changed labels, but in this case, I don't know how it could be fair to let the fact be known, let the jury know that this drug is still on the market without letting them know there's been a changed warning. It puts too big of a gravel in my shoe."). Order on motions in limine, *Wilson v. Wyeth*, Case No. 05-78 (E.D. Ark., Sept. 24, 2010) ("If Defendants inform the jury that Prempro is still on the market, Plaintiffs can introduce the fact that it is on the market with a substantially changed warning. Plaintiffs can introduce specifically pertinent parts of the warning that now accompany the drug. I realize that a changed warning is usually excluded under Federal Rule of Evidence 407, but I am convinced that, in this specific instance, the warning would be 'offered for another purpose.' Defendants should submit a written proposed limiting instruction if they want one.").

Motion *in Limine* No. 14: To preclude Defendants from offering argument, evidence, or testimony regarding the AUGS/SUFU Stress Urinary Incontinence Sling "Position Statement" – DX20155.

Plaintiff moves to preclude any argument, evidence or testimony relating to the AUGS/SUFU[6] "Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence" ("Position Statement") for the reasons and based on the authority cited below. Defendants seek to rely on a demonstrably unscientific, litigation-driven, Position Statement, a copy of which is attached hereto as **Exhibit 12**, which generally alleges that (1) polypropylene is safe and effective; (2) polypropylene SUI slings have been studied extensively; and (3) polypropylene mesh is the "standard of care" for SUI treatment.[7] The goal of this "Position Statement" is clear: to defend against mesh litigation.[8]

As one of the authors of the Position Statement testified, it was never intended to be any sort of scientific undertaking or objective analysis:

> Q. This is not a review of peer-reviewed published medical literature in an effort to then report on some conclusion of that review?

[6]American Urogynecologic Society ("AUGS") and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction ("SUFU").

[7] The Position Statement further states "[L]awyers have publicly advertised their services, targeting women with transvaginal mesh placed for both pelvic organ prolapse and stress urinary incontinence (SUI), and the media has reported on the pelvic organ prolapse mesh litigation. We are concerned that the multimedia attention has resulted in confusion, fear, and an unbalanced negative perception regarding the midurethral sling as a treatment for SUI."

[8] One of the Position Statement authors stated in an e-mail: "A document someone could point to in their own lawsuit may be another value add. Doctors are being named on lawsuits that are ultimately intended for the manufacturer, but the doctor is getting dragged in to keep the case in state court…. This document would help them." (**Exhibit 13**). Minutes of a December 5, 2013, MUS Task Force Meeting state, "Polypropylene mesh midurethal sling for stress urinary incontinence is getting a bad image. Class action lawyers are stating that the material that is defective…. We have seen frustration from our members and need to provide resources to assist them in conversations with patients, media, and lawyers/lawsuits," and "[w]e want our members to use this position statement at legal proceedings." (**Exhibit 14**). A January 7, 2014, AUGS/SUFU correspondence to members stated that "[w]ith this statement we hope to clarify the confusion that has resulted from the advertisements by lawyers recruiting women with transvaginal mesh placed for both prolapse and incontinence." (**Exhibit 15**). A January 9, 2014, e-mail between MUS Task Force members stated, "I have received any number of very positive responses on the position statement and I can tell you it was already used to counter those who are employing legal means to eliminate slings." (**Exhibit 16**).

A. Right.

Q. This is a report developed by the five authors as a position statement just regarding slings?

A. This is a position statement of two large medical societies of doctors about slings for stress urinary incontinence. And so it only reflects the position of those two societies.

Q. But it does not reflect a scientific analysis of the published literature?

A. No.

Q. We can agree on that?

A. We can – we absolutely can.

(Ex. 17 – Deposition Transcript - Miller at 539:19-540:13).

This co-author also admitted that the Position Statement is litigation-driven:

Q. And you wanted to make a document someone could point to in their own lawsuit, correct?

A. That – that would be – **yes** . . .

Q. And so one of the purposes of this position statement was to produce something that a doctor could point to in their own lawsuit?

. . .

THE WITNESS: **It's one of the out – it would be one of the outcomes of it**.

(*Id*. at 533:6-353:15).

The wholly irrelevant, litigation-driven, rank hearsay, and admittedly unscientific "Position Statement" created by a self-interested group of doctors attempting to protect industry members should not be admitted in this case.

The Position Statement is nothing more than a litigation-driven position statement intended for use in litigation – to protect doctors' and mesh manufacturers' own financial self-interests. The Eleventh Circuit recently held in no uncertain terms in *Adams v. Lab. Corp. of America*, 760 F.3d

1322 (11th Cir.2014), that this sort of litigation-driven "position statement" cannot be allowed to usurp the role of the factfinder.[9] In *Adams*, the Eleventh Circuit properly instructed that "neither *Daubert* nor *Kumho* permits a scientific or medical community to define a 'litigation standard'…." The court in *Adams* further observed as follows:

> With their guidelines for litigation, the [medical societies] moved away from disinterested scientific inquiry and into litigation policy to serve their members' own interests. However much the members of those associations may accept and even applaud the move, it is not scientific acceptance, which is what *Daubert* involves. Nor is litigation policy "the practice of an expert in the relevant field," as *Kumho* thought of it. *See Kumho,* 526 U.S. at 152 (stating that the district court's gatekeeper function is meant to ensure that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"). The district court's ruling runs afoul of those two decisions, which do not permit delegating to industry groups the gatekeeping duties of the courts.
>
> If the [medical societies] can define what constitutes admissible expert testimony in their members' professional negligence cases, then there is no apparent reason why other groups whose members face lawsuits cannot do the same…. They can't because courts do not allow interested groups to set evidentiary or other litigation standards.

The Position Statement purports to dictate not only the "standard of care," but also to decide the safety and efficacy of a material, generally, and of an entire category of medical devices – even though those devices have injured tens of thousands of women. This Position Statement would also usurp the role of the jurors that will decide this case. Whether or not these devices are safe and effective, to quote *Adams*, "of course, is a decision to be made by courts, not by self-interested associations."[10]

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[9] The Eleventh Circuit reversed the trial court's grant of summary judgment to the defendant, in part because the district court improperly relied on a litigation position statement by an interested professional organization.

[10]As the Court instructed in *Adams*, the standard of care "of course, is a decision to be made by courts, not by self-interested associations." The same is true here – whether polypropylene mesh is any sort of "standard," or whether it is "safe and effective," as the Position Statement alleges, is for the juries hearing these cases to decide – not AUGS or SUFU or any other interest group.

Finally, Plaintiff points out that Ethicon is a member of the "Industry Council" for AUGS and has paid AUGS a total of $587,865.00 and has paid SUFU $154,375.00 – specifically related to pelvic floor, gynecology, or urinary tract conditions/surgery. (*See*, Spreadsheet produced by Defendants showing payments, copy attached hereto as **Exhibit 18**).[11] Thus, the Position Statement is nothing more than a self-serving statement by a group to which the Defendants belong – admittedly created to defend these corporate group members in this litigation. It would be no different from Plaintiff attempting to introduce a Position Statement from a group of mesh victims denouncing mesh. Instructively, the Defendants have moved to exclude any statements from outside groups that they deem adverse to their litigation position – including an anti-mesh letter from "Public Citizen," which Ethicon called an "advocacy group."[12] Seeking to exclude such statements, while simultaneously urging admission of the Position Statement at issue here, is disingenuous.

The Position Statement, and any similar out-of-court statement by an advocacy group, must be excluded from evidence, and no reference or argument based thereon should be allowed.

[11] Plaintiffs would also be unduly prejudiced by admission of the Position Statement. Valuable trial time will need to be spent to combat this hearsay statement, thus creating a sideshow about the motivations of the authors and their relationship to the Defendants. Moreover, the jury will be prevented from hearing the complete truth about Ethicon's involvement in and influence over the groups that created this litigation-driven Position Statement. This evidence will confuse and mislead the jury, which will assume that these are disinterested medical professionals who created this on their own accord, which could not be further from the truth.

[12] *See, e.g.*, Ex. 19 - *Bellew v. Ethicon, Inc., et al.*, Case 2:13-cv-22473, Dkt. No. 207 (Defendants' Omnibus Motion *in Limine*, MIL No. III – "The Court should exclude evidence of anecdotal case reports or case series"; MIL No. VII – "The Court should exclude a 2008 physician survey conducted by a consulting group"; MIL XVI(B) – seeking exclusion of Institute of Medicine Report and Public Citizen (referred to as an "advocacy group") letter to the FDA)).

Motion *in Limine* No. 15: To preclude Defendants from offering argument, evidence, or testimony referencing any Advisory Committee recommendations.

An FDA Advisory Committee is not an official governmental agency and recommendations of such a committee are not rules, statutes, or ordinances. There is no rule or law authorizing admissibility of such recommendations and any such recommendations are not relevant. F.R.E. 402, 802, 803. Further, such reference to any such recommendations would be unduly prejudicial and confusing to the jury and would result in a "trial within a trial." F.R.E. 403.

In fact, in the New Jersey state court *Gross* case, which involved a pelvic organ prolapse product, Ethicon sought to exclude reference to these same documents based on this same argument, urging that "there is a very real danger that the jury will view [the Advisory Committee's conclusions] as a final agency determination as to the safety or effectiveness of transvaginal mesh" which it urged "[w]ould be an unfair characterization." Defendants should not be allowed to now take advantage of the Advisory Committee conclusions or action/inaction in this case.

Motion *in Limine* No. 16: To exclude argument or testimony related to the "Time to Rethink" Article – DX30675.

In 2011, Ethicon consultants (Miles Murphy, Vincent Lucente, and Heather Van Realte) and a Boston Scientific consultant, Adam Holzberg, wrote an opinion piece which was published in the International Urogynecology Journal. (Murphy M et al. *Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse."* Int Urogynecol J 2012; 23: 5-9.). The article, attached hereto as Ex. 20, is an unscientific, propaganda opinion piece, and should not be referenced at trial.

The purpose of the article was to address "The Recent FDA Update" (July 2011) and show that some doctors felt that all mesh repairs should not be banned, without reference to or analysis of a specific device or system. The authors circulated a petition that was signed by 600 doctors confirming that they agree mesh in general should not be completely banned. There is no information as to why each doctor signed the petition. In addition, the article was not peer-reviewed. Rather, it is an opinion piece, or editorial, and not a scholarly article. In fact, the group submitting the article, the "Pelvic Surgeons Network," was a name made up by Miles Murphy and Vince Lucente. (Exhibit 21 – Deposition Transcript - Vincent Lucente, MD 11/2/12 at 278:17-279:24).

Presenting evidence to the jury that 600 doctors merely signed a petition, without additional support or information, lacks foundation and would be very misleading and unduly prejudicial to the plaintiff. *See* F.R.E. 403. Since the article is general in scope, and not specific to the device at issue in the present case, it is wholly irrelevant, and at best misleading and confusing. *See* F.R.E. 401, 402, 403. For these reasons, the "Time to Rethink" article should not be referenced or relied

on at trial. Another court in a similar trial has previously excluded this article[13] and the Plaintiff requests that the court adopt the same ruling in this matter.

[13] *Bellew v. Ethicon, Inc*., No. 2:13-cv-22473, 2014 U.S. Dist. LEXIS 165709, at *8 (S.D. W. Va. Nov. 25, 2014) ("The following motions by the plaintiff are **GRANTED**: Motion *in Limine* No. 3: To Exclude the "Time to Rethink" Article).

Motion *in Limine* No. 17: The Defendants should not be permitted to suggest that Plaintiff is guilty of negligence or to argue comparative fault.

Plaintiff moves to preclude any argument, testimony, or evidence of any type relating to any patient-specific evidence or physician conduct. The Court should exclude any evidence or argument regarding patient-specific evidence, such as co-morbidities, pre-existing health or medical conditions, patient lifestyle or conduct, and any evidence relating to any physician conduct, as irrelevant and unfairly prejudicial under Federal Rules of Evidence 401 and 403. There is no expert opinion or competent evidence that the plaintiff was negligent in any way in this case. Therefore, no suggestions should be made that the plaintiff was comparatively at fault or responsible for her injuries.

One of the Defendants' consistent arguments throughout this litigation has been that their products did not cause the Plaintiff's injuries, and that something else caused it – either the implanting doctor, or the Plaintiff herself, or both. However, under Defendants' view, any untoward result would never be their products' fault. The Defendants' "Master Answer" contains several defenses that point the finger directly at the Plaintiff and/or their doctors. (*See, e.g.*, MDL Dkt. No. 218-4 (Master Answer), Fortieth Defense; Forty-First Defense; Forty-Second Defense; Forty-Third Defense; Forty-Fourth Defense; Forty-Sixth Defense; Forty-Eighth Defense; Forty-Ninth Defense; Fiftieth Defense).

As another example, at the September 2011 FDA hearing addressing serious concerns about the safety of transvaginal mesh devices, Ethicon's Worldwide Medical Affairs Director for Women's Health and Urology, Piet Hinoul, testified that the complications associated with these devices are always the result of either patient factors and/or doctor experience (i.e., it's not the product's fault), stating "One of the most important questions we need to ask ourselves is also why

these adverse events are occurring. And the risk factors for mesh exposures are becoming more and more apparent. Several studies published this year show that hysterectomy, patient age, smoking, diabetes, and surgeon experience predispose patients to mesh exposure." (Excerpt of FDA hearing transcript attached hereto as **Exhibit 22, at p. 145**). Any such evidence or argument regarding patient-specific factors, patient conduct, or any physician conduct in this design defect consolidated trial should be excluded as irrelevant, and furthermore, as violative of nearly every principle of Rule 403.

Therefore, any evidence or argument about co-morbidities or any medical condition, doctor conduct, or any other type of patient-specific factors should be excluded as irrelevant here.

Federal Rule of Evidence 403 provides that "[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Any evidence or argument about patient-specific factors, physician conduct, or co-morbidities would unduly prejudice the Plaintiff, and would unnecessarily delay the trial and would confuse and mislead the jury. Thus, to allow Defendants to make any argument or to present any evidence about any patient-specific factors (such as co-morbidities or surgeon error) would cause undue prejudice. In addition, allowing the defense to present this sort of irrelevant and prejudicial patient-specific evidence would only serve to delay the trial and waste limited trial time. Even if this matter were not excluded as irrelevant and immaterial, it should be excluded under Rule 403.

Furthermore, there is no expert opinion or competent evidence that the Plaintiff was negligent in any way in this case. Therefore, no suggestions should be made that the Plaintiff was comparatively at fault or responsible for her injuries. Thus, this matter should be excluded.

Motion *in Limine* No. 18: To exclude any evidence of payments which have been or may have been made by health insurers or others of medical bills or of wage related benefit or payment (Collateral Source Rule).

This exclusion would include, but not necessarily be limited to, evidence of payments by Medicare, Medicaid, private insurance, Social Security, disability carriers and the like. Such payments constitute collateral source evidence and thus may not be mentioned. *See Southern v. Plumb Tools, Div. of O'Ames Corp.,* 696 F.2d 1321, 1323 (11th Cir. 1983) ("Alabama strictly adheres to the collateral source rule with respect to insurance payments and workmen's compensation benefits, and any showing that Plaintiff has received such payments constitutes reversible error.")(citing *Jones v. Crawford*, 361 So.2d 518 (Ala.1978); *Gribble v. Cox*, 349 So.2d 1141 (Ala.1977); *Vest v. Gay*, 275 Ala. 286, 154 So.2d 297 (1963); *Coleman v. Hamilton Storage Co*., 235 Ala. 553, 180 So. 553 (1938)).

Defendants have generally not opposed this motion in the past and other Courts have granted it. *See Bellew v. Ethicon, Inc.*, Civ. Act. No. 2:13-cv-22473, 2014 WL 6680356, at *8 (S.D.W. Va. Nov. 25, 2014).

Motion *in Limine* No. 19: To preclude Defendants and defense counsel from presenting evidence related to personal problems that Ms. Ruberti experienced through the course of her life.

Defendants' only possible argument regarding these events is that they are relevant to plaintiff's mental anguish claims. There are three independent problems with that argument.

First, these events are far too temporally distant to be relevant to any claim. They happened many years ago.

Second, plaintiff is making only a mental anguish or "garden variety" emotional distress claim. Plaintiff does not claim that she suffers from a psychic injury or psychiatric disorder caused by her use of the TVT-O, such that other possible causes of such mental illness might somehow come into play. Rather, Plaintiff claims she suffers the mental anguish that expectedly accompanies the kind of severe physical pain caused by the injuries she suffers. "The majority of courts have held that plaintiffs do not place their mental condition in controversy merely by claiming mental anguish or 'garden variety emotional distress." *Stevenson v. Stanley Bostitch, Inc.*, 201 F.R.D. 551, 553 (N.D. Ga. 2001); *accord Ortiz-Carballo v. Ellspermann*, No. 5:08-cv-165-Oc-10GRJ, 2009 WL 961131, at *2 (M.D. Fla. Apr. 7, 2009). Such claims do not even open the door to discovery of a plaintiff's mental condition, let alone the admission of evidence about her mental state. *Gropper v. David Ellis Real Estate, L.P.*, No. 13 Civ.2068(ALC)(JCF), 2014 WL 642970, at *2 (S.D.N.Y. Feb. 14, 2014) (denying discovery of medical records).

Finally, the evidence is far too prejudicial to be admissible, even if it were somehow tangentially related to Plaintiff's damages (which it is not). The evidence is thus inadmissible. F.R.E. 403.

Motion *in Limine* No. 20: To preclude Defendants and defense counsel from providing evidence or testimony related to Plaintiff's mental health records or treatment.

For the reasons just given, Debra Ruberti's mental health records should not be admitted or referred to, without a particularized showing of justification. Again, Ms. Ruberti is claiming only mental anguish/garden variety emotional distress. She claims only the anguish that ordinarily accompanies severe physical pain.

The fact that Ms. Ruberti may have suffered psychic injury or psychological trauma in the past does not somehow detract from the anguish associated with her physical pain now. At the very least, defendants should be required to approach the bench and secure a ruling before introducing evidence from, or referring to, Ms. Ruberti's mental health records pursuant to F.R.E. 401 and 403.

Motion *in Limine* No. 21: To preclude Defendants and defense counsel from providing evidence or testimony related to Plaintiff's social security disability and long-term disability benefits claims.

Ms. Ruberti successfully filed a disability claim through the Social Security Administration ("SSA") subsequent to resigning from her last job. The claim was initially denied and then later approved. Additionally, her insurance carrier at that time, Mutual of Omaha, initially denied an application for disability benefits, which was also later approved. Evidence of her filing of disability claims with her insurance provider and through SSA, are inadmissible as these matters could only be used to prejudice the jury into believing plaintiff is litigious. Those applications and the subsequent decisions of those agencies have no bearing on the validity and severity of plaintiffs' injuries related to the TVT-O device at issue in this case. Any argument regarding what the initial denials, and the later approvals by those agencies might mean would be speculation, based on inadmissible hearsay evidence, and would take the jury, and the trial, down a meaningless rabbit hole. F.R.E. 401, 402, 403, 602, 802.

Motion in Limine No. 22: **That Defendants and their counsel be precluded from reference to other medical conditions of Plaintiff's without competent evidence, based on reasonable medical probability, that the conditions caused the injuries at issue in this case**.

Debra Ruberti underwent medical treatment for injuries other than those at issue in this lawsuit both prior and subsequent to the April 16, 2012, implantation of the TVT-O and the subsequent removal procedures on January 14, 2013, and October 29, 2013. Among these are back surgery, knee surgery, and other procedures. None of these medical conditions - or the treatment of those medical conditions - is relevant to the issues in this case. The defense should not be permitted to confuse or mislead the jury with discussion of these unrelated conditions and the treatment thereof. F.R.E. 401, 403. At the very least, defendants should be required to approach the bench and secure a favorable ruling before attempting to divert the jury's attention from the injuries at issue to other conditions.

A causal connection must be based upon 'reasonable medical probability,' not mere conjecture, speculation, or possibility. *See e.g., Biggs v. Clyburn*, 2003 Tex. App. LEXIS 4369 *12 (Tex. App. Houston [1st Dist.] May 22, 2003). Any such reference would not be relevant and would be unfairly prejudicial. FRE. 403.

Motion in Limine No. 23: Motion to Preclude Improper Deposition Designations.

The Plaintiff seeks to preclude Defendants from (1) affirmatively designating deposition testimony of available witnesses; and (2) counter-designating deposition testimony, unless narrowly limited to testimony necessary for completeness and context of the Plaintiff's affirmative designations.

Motion in Limine No. 24: **To preclude Defendants and their counsel from offering argument, evidence, or testimony referring to details of Plaintiff's law firm.**

No party shall, as part of any trial, any *voir dire,* or any other proceedings in the presence of any jury empaneled for any trial, refer to any party's fee agreement, including, but not limited to, who is paying expenses or who is responsible for expenses in connection with this litigation; or the date or circumstances under which Plaintiff employed her attorneys; or the name of any other lawyer retained or consulted by Plaintiff, whether or not such lawyers were the original attorneys of record and whether such lawyer or any other lawyer referred her to the undersigned attorneys.

Motion in Limine No. 25: To Exclude Statements about Counsel.

Counsel is not on trial in this case. Nor will counsel be testifying. Thus, any statements attacking counsel personally, or suggesting that counsel has driven this litigation through lawyer advertisements, would be irrelevant and inherently prejudicial, given jurors' inherent distrust of lawyers. F.R.E. 401-03.

Defendants have not disputed this in the past and other courts have thus granted this motion, at least insofar as comments about lawyers are concerned. *See Lewis v. Ethicon*, Nos. 2:12-MD-02327, 2:12-cv—4301, 2014 WL 505234, at *3 (S.D.W. Va. Feb. 5, 2014). The evidence is unduly prejudicial in that it would encourage the jury to render a verdict based on its opposition to lawyers and their advertising rather than their conclusions regarding the issues in this litigation. F.R.E. 403.

Respectfully submitted,

By: */s/ Gabriel A. Assaad*

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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I certify that on October 17, 2022, I electronically filed the foregoing with the clerk of the court which sent notifications to all registered parties via CM/ECF.

/s/ Gabriel A. Assaad
Gabriel A. Assaad